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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,633	10/14/2003	Michael S. Kopreski	00-1312-L	5239
7590	01/28/2008	McDonnell Boehnen Hulbert & Berghoff 32nd Floor 300 S. Wacker Drive Chicago, IL 60606	EXAMINER LU, FRANK WEI MIN	
			ART UNIT 1634	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/684,633	KOPRESKI, MICHAEL S.
	Examiner	Art Unit
	Frank W. Lu	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 October 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3,5-11,13,14 and 16-28 is/are pending in the application.
 4a) Of the above claim(s) 5-10 and 17-28 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3,11,13,14 and 16 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on October 29, 2007 have been entered. The claims pending in this application are claims 1, 3, 5-11, 13, 14, and 16-28 wherein claims 5-10 and 17-28 have been withdrawn due to restriction requirement and species election requirement made on April 28, 2006. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on October 29, 2007. Therefore, claims 1, 3, 11, 13, 14, and 16 will be examined.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. New Matter

Claims 14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation “detecting response to said therapy when a decreased amount of her-2/neu RNA is detected” is added to the newly amended independent claim 14. Although the specification describes that a woman with metastatic breast cancer is treated with a monoclonal antibody that binds with the extracellular domain of her-2/neu, and a cytotoxic chemotherapeutic agent such as a taxane that is known to be synergistic with the monoclonal antibody. The woman’s response to therapy is consequently determined by serially monitoring in a quantitative fashion levels of her-2/neu RNA in the women’s plasma or serum (e.g., see the specification, page 25, example 1), the specification fails to define or provide any disclosure to support such claim recitation. Furthermore, in applicant’s remarks filed on October 29, 2007, applicant does not indicate which part in the specification supports such claim recitation.

MPEP 2163.06 notes “IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.” MPEP 2163.06 further notes “WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT “NEW MATTER” IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*” (emphasis added).

4. Scope of Enablement

Claims 1, 3, 11, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting her-2/neu RNA in plasma or serum in certain human cancer patients, does not reasonably provide enablement for (1) using the method recited in claim 1 for detecting two or more species of RNA together wherein the two or more species of RNA are epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B1 RNA in human blood plasma or serum; (2) using the method recited in claim 3 for specifically detecting her-2/neu RNA; and (3) using the methods recited in claims 11 and 13 for evaluating a human having any kind of cancer for a her2/neu-directed therapy by assaying quantitatively or qualitatively blood plasma or serum from the human for her-2/neu RNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to show that: (1) the method recited in claim 1 can be used for detecting two or more species of RNA together

wherein the two or more species of RNA are epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B1 RNA in human blood plasma or serum;(2) the method recited in claim 3 can be used for specifically detecting her-2/neu RNA; and (3) the methods recited in claims 11 and 13 can be used for evaluating a human having any kind of cancer for a her2/neu-directed therapy by assaying quantitatively or qualitatively blood plasma or serum from the human for her-2/neu RNA. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether: (1) the method recited in claim 1 can be used for detecting two or more species of RNA together wherein the two or more species of RNA are epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B1 RNA in human blood plasma or serum;(2) the method recited in claim 3 can be used for specifically detecting her-2/neu RNA; and (3) the methods recited in claims 11 and 13 can be used for evaluating a human having any kind of cancer for a her2/neu-directed therapy by assaying quantitatively or qualitatively blood plasma or serum from the human for her-2/neu RNA.

Claim 1 is directed to a method for detecting two or more species of RNA together wherein the two or more species of RNA are epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, and heterogeneous nuclear ribonucleoprotein A2/B1 RNA by amplifying two or more species of RNA together wherein the two or more species of RNA are epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, and heterogeneous nuclear ribonucleoprotein A2/B1 RNA in blood plasma or serum from any kind of human. First, since claim 1 does not require that human blood

plasma or serum is from a normal human or a human with a specific cancer, it is known that some of cancers such as Hodgkin and Hon-Hodgkin lymphoma do not have overexpression or even any expression of her-2/neu RNA (see abstract in page 574 of Arch. Pathol. Lab. Med., 126, 574-576, 2002) while c-myc mRNA is overexpressed in Hon-Hodgkin lymphoma (see page 2087, abstract, page 2089, left column, last paragraph and page 2090, Table 2 from Hernández et al., Leukemia, 13, 2087-2093, December 1999), when human blood plasma or serum is from human with Hon-Hodgkin lymphoma, it is unclear how to detect her-2/neu RNA and c-myc RNA together by amplifying her-2/neu RNA and c-myc RNA in blood plasma or serum. Second, since the specification does not provide guidance to show that two or more RNAs selected from epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, and heterogeneous nuclear ribonucleoprotein A2/B1 RNA can be detected together in human blood plasma or serum, it is unclear how to amplify two or more RNAs selected from epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, and heterogeneous nuclear ribonucleoprotein A2/B1 RNA as recited in claim 1.

Claim 3 is directed to a method for hybridizing her-2/neu RNA from blood plasma or serum from a human with breast cancer or cDNA produced therefrom using a probe that hybridizes with her-2/neu RNA (ie., Erbb) or cDNA produced therefrom. Since claim 3 does not require that the probe only specifically hybridizes with human her-2/neu RNA and it is known that mRNA contains a poly(A) tail, when the probe recited in claim 3 is poly(T), the method recited in claim 3 cannot be used for specifically detecting her-2/neu RNA.

Claims 11 and 13 are directed to a method for evaluating a human having any kind of cancer for a her2/neu-directed therapy by assaying quantitatively or qualitatively blood plasma or

serum from the human for her-2/neu RNA. Since it is known that some of cancers such as Hodgkin and Hon-Hodgkin lymphoma do not have overexpression or even any expression of her-2/neu RNA (see abstract in page 574 of Arch. Pathol. Lab. Med., 126, 574-576, 2002) and the claims do not limit that the human is a human having a specific cancer, it is unclear how to evaluate a human with Hodgkin and Hon-Hodgkin lymphoma for a her2/neu-directed therapy by assaying quantitatively or qualitatively blood plasma or serum from the human for her-2/neu RNA. Furthermore, the specification does not show that her2/neu-directed therapy can be used in any kind of cancer as recited in claims 11 and 13.

With above unpredictable factor, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. The undue experimentation at least includes to test whether: (1) the method recited in claim 1 can be used for detecting two or more species of RNA together wherein the two or more species of RNA are epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B1 RNA in human blood plasma or serum; (2) the method recited in claim 3 can be used for specifically detecting her-2/neu RNA; and (3) the methods recited in claims 11 and 13 can be used for evaluating a human having any kind of cancer for a her2/neu-directed therapy by assaying quantitatively or qualitatively blood plasma or serum from the human for her-2/neu RNA.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 11, 13, 14, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is rejected as vague and indefinite. Although claim 1 is directed to a method for detecting one or more species of RNA that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B1 RNA in human blood plasma or serum, from the claim, it is unclear which situation indicates that one or more species of RNA that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B1 RNA in human blood plasma or serum is detected. Please clarify.

8. Claim 3 is rejected as vague and indefinite because it is unclear hybridizing her-2/neu RNA or cDNA produced therefrom to what. Please clarify.

9. Claim 11 is rejected as vague and indefinite because, from the claim, it is unclear what is a standard for evaluating a human having a cancer for a her2/neu-directed therapy. Please clarify.

10. Claim 14 is rejected as vague and indefinite because it is unclear that the amount of her-2/neu decreases is due to the response to the therapy or not. Please clarify.

11. Claim 14 recites the limitation "the human with breast cancer receiving a her-2/neu directed therapy" in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase "human with breast cancer receiving a her-2/neu directed therapy" before "the human with breast cancer receiving a her-2/neu directed therapy". Please clarify.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Balazs *et al.*, (WO 90/09456, published on August 23, 1990).

Regarding claim 1, Balazs *et al.*, teach a method for detecting one or more species of RNA that is epidermal growth factor receptor RNA or c-myc RNA, the method comprising the steps of: a) extracting total extracellular RNA from a human blood plasma or serum, wherein a fraction of said extracted RNA comprises one or more RNA species that is epidermal growth factor receptor RNA (ie., Erb^B RNA) or c-myc RNA; b) amplifying or signal amplifying said fraction of the extracted RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers or probes specific for said RNA species to produce an amplified product or using labeled primers or probes specific for said RNA species to produce an amplified signal; and c) detecting either quantitatively or qualitatively the amplified product or amplified signal as recited in claim 1 (see pages 14-19).

Therefore, Balazs *et al.*, teach all limitations recited in claim 1.

Response to Arguments

In page 8, third paragraph bridging to page 10, last paragraph of applicant's remarks, applicant argues that: (1) “[A]pplicant respectfully contend that the teachings of the Balazs reference do not enable nor anticipate Applicant's claims, because they do not teach extraction of

total extracellular RNA from plasma or serum"; (2) "the Balazs reference requires the inactivation of such ribonucleases by adding an RNase inhibitor prior to isolating plasma as a condition for detecting RNA from plasma"; (3) "the methods taught in the instant specification do not require addition of an RNase inhibitor prior to separation of plasma. This is because by adding an RNase inhibitor prior to separation of the cellular and acellular fractions of blood, any method incorporating such RNase inhibitors will stabilize any *intracellular* RNA released from cells during the separation process, and thus provide contaminating intracellular RNA into the plasma. One of ordinary skill would recognize this deficiency in the method disclosed in the Balazs reference, and would understand that as a consequence Balazs does not teach a method that could be used to (unambiguously) detect extracellular RNA in blood plasma. The instant inventor found, surprisingly, that extracellular RNA is sufficiently stable even in the presence of RNases so as to be detectable in human blood plasma or serum without adding RNase inhibitors; indeed, this is evidenced by detection of extracellular RNA species using the methods disclosed in the instant specification. Adding RNases to blood prior to separating the cellular from the acellular portions thereof is unnecessary to stabilize extracellular RNA, but can be expected to stabilize intracellular RNA inadvertently-released from blood cells during separation. The Balazs reference recognizes that intracellular RNA contamination should be avoided, but provides no teachings on how blood separation methods can be modified to prevent it"; and (4) "there is no teaching in the Balazs reference for detecting extracellular RNA in serum, which is produced from blood by permitting the blood to clot. Moreover, under the circumstances of clotting it would be expected by the skilled worker that intracellular RNA would be released and stabilized by the introduction (as taught by Balazs) of RNases to whole blood. Thus, the application of the

Balazs teachings to serum (not taught by Balazs) would produce a sample likely to be extensively contaminated by intracellularly-derived RNA species”.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, Balazs *et al.*, do teach extraction of total RNA from blood plasma including total extracellular RNA (see page 14). Second, although the examiner agrees with applicant “the Balazs reference requires the inactivation of such ribonucleases by adding an RNase inhibitor prior to isolating plasma as a condition for detecting RNA from plasma”, claim 1 does not require extracting total extracellular RNA from human blood plasma or serum without adding an RNase inhibitor as argued by applicant. Third, claim 1 does not require directly detecting extracellular RNA in serum as argued by applicant.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs *et al.*, as applied to claim 1 above, and further in view of Revillion *et al.*, (Clinical Chemistry, 43, 2114-2120, 1997).

Regarding claim 3, Balazs *et al.*, teach a method for hybridizing epidermal growth factor

receptor RNA (ie., Erbb) from blood plasma from a human with a cancer or cDNA produced therefrom using a probe (ie., the primers) that hybridizes with epidermal growth factor receptor RNA (ie., Erbb) or cDNA produced therefrom (see pages 5 and 14-19).

Balazs *et al.*, do not disclose that RNA is her-2/neu RNA as recited in claim 3. Note that her-2/neu is one of epidermal growth factor receptors.

Revillion *et al.*, teach to RT-PCR her-2/neu (erbB-2) gene in the presence of her-2/neu primers (see pages 2115 and 2116).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have hybridized her-2/neu RNA from blood plasma from a human with a breast cancer or cDNA produced therefrom using a probe (ie., the primers) that hybridizes with her-2/neu RNA or cDNA produced therefrom as recited in claim 3 in view of references of Balazs *et al.*, and Revillion *et al.*. One having ordinary skill in the art has been motivated to do so because Revillion *et al.*, have successfully amplified her-2/neu (erbB-2) gene in the presence of her-2/neu primers by RT-PCR (see pages 2115 and 2116). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to hybridize her-2/neu RNA from blood plasma from a human with a breast cancer or cDNA produced therefrom using a probe (ie., the primers) that hybridizes with her-2/neu RNA or cDNA produced therefrom in view of references of Balazs *et al.*, and Revillion *et al.*.

Response to Arguments

In page 11 of applicant's remarks, applicant argues that "[T]he deficiencies of the Balazs reference are set forth above. In addition, in the context of non-obviousness the Balazs reference

suffers from the following additional deficiencies. The reference does not negate the findings of the art as a whole (such as the Komeda and Pfleiderer reference) that extracellular RNA could not exist in blood plasma or serum under the constant presence of circulating ribonucleases. Instead, the reference suggests that ribonucleases would degrade any RNA found in plasma, as understood by the art, unless an RNase inhibitor was added prior to separating the cellular and acellular portions of blood. In contrast, Applicant's specification teaches that extracellular RNA can be detected in plasma without requiring nuclease inhibitors being added to whole blood prior to separation. This teaching of the instant specification was surprising and unexpected in view of the prior art as a whole, and specifically in view of the Balazs reference, since it was contrary to the notion that extracellular RNA was not detectable in blood plasma or serum due to blood ribonucleases. The understanding of the art, including the Balazs reference, is relevant because it motivated Balazs to introduce RNase inhibitors to blood prior to separating blood cells from plasma, resulting in a plasma-RNAase inhibitor mixture wherein intracellular RNA released from blood cells 'broken' during the separation process would have become detectable following the inactivation of naturally occurring RNases. The teachings of the Revillion reference do not overcome the deficiencies of the Balazs reference. Moreover, the publication date of this reference (1997) is after the claimed priority date of the instant application (1996). Thus, the Revillion reference is not prior art to Applicant's invention. However, Applicant respectfully contends that, even if the teachings of the Balazs reference are taken in combination with the Revillion reference his claimed invention is non-obvious, for the reasons set forth herein".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, although the examiner agrees with applicant "[A]pplicant's

specification teaches that extracellular RNA can be detected in plasma without requiring nuclease inhibitors being added to whole blood prior to separation", claim 1 does not require extracting total extracellular RNA from human blood plasma or serum without adding an RNase inhibitor as argued by applicant. Second, since US provisional application 60/014,730 does not describe her-2/neu, the priority date of this instant applicant was not March 26, 1996. Therefore, the reference from Revillion *et al.*, is a prior art.

Conclusion

16. No claim is allowed.
17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

January 15, 2008



FRANK LU
PRIMARY EXAMINER